The effectiveness of percutaneous transluminal angioplasty for the treatment of critical limb ischemia: A 10-year experience

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Objective: **To determine the efficacy, safety, and long-term results, including continued clinical improvement and limb salvage, of percutaneous transluminal angioplasty (PTA) in patients with critical limb ischemia (CLI).**

Methods: **From August 1993 to March 2004, 138 limbs in 111 patients with CLI (rest pain in 62 [45%] and ulcer/gangrene in 76 [55%]) were treated by PTA. In iliac lesions, stents were placed selectively for primary PTA failure: residual stenosis (>30%) or pressure gradient (>5 mm Hg). Stent placement was limited in infrainguinal lesions. The most distal affected arteries treated with angioplasty were the iliac artery in 45 limbs (33%; iliac group), the femoropopliteal artery in 41 limbs (30%; FP group), and tibial arteries in 52 limbs (37%; BK group). All analysis was performed according to an intent-to-treat basis. Reporting standards of the Society for Vascular Surgery and the International Society for Cardiovascular Surgery were followed to evaluate initial success, and late follow-up status was evaluated with the Kaplan-Meier method. Patency was evaluated by using ultrasound scanning and ankle-brachial pressure index measurement.**

Results: **There was one (0.9%) perioperative death. Twenty stents were placed selectively in 14 iliac arteries. Mean follow-up was 14.7 months (range, 1-75 months). Overall, initial technical and clinical success rates were 96.4% and 92.8%, respectively. The cumulative primary, assisted primary, and secondary patency; continued clinical improvement; and limb salvage rates ± SE at 5 years were 31.4% ± 10.4%, 75.5% ± 5.7%, 79.6% ± 5.5%, 36.1% ± 10.0%, and 89.1% ± 4.0%, respectively. In each subgroup, the primary, assisted primary, and secondary patency; continued clinical improvement; and limb salvage rates at 3 years were 51.6%, 94.7%, 97.8%, 65.1%, and 95.0%, respectively, in the iliac group; 49.4%, 72.2%, 76.4%, 57.4%, and 92.7%, respectively, in the FP group; and 23.5%, 41.8%, 46.1%, 51.1%, and 77.3%, respectively, in the BK group. Of the 12 predictable variables, hypertension, multiple segment lesions, more distal lesions, and TransAtlantic Inter-Society Consensus classification type D were significant independent risk factors for the outcomes (*P* < .05; univariate log-rank test and Cox regression multivariate analysis).**

Conclusions: **PTA is a feasible, safe, and effective procedure for the treatment of CLI. The high limb salvage rate is attributed to the high assisted primary and secondary patency rates despite the low primary patency rate. Angioplasty can be the primary choice for the treatment of CLI due to iliac and infrainguinal arterial occlusive disease. (J Vasc Surg 2005;41:423-35.)**

Critical limb ischemia (CLI) has been considered as a primary indication for bypass surgery.[1-3] Because of compromised hemodynamic success or patency rates after percutaneous transluminal angioplasty (PTA) in patients with CLI, some investigators have suggested that PTA in these patients should be confined to unusual circumstances, such as high risk for surgery or no autogenous bypass material available.[1-3] In recent years, with continuing advances in imaging techniques, angioplasty equipment, and endovascular expertise, the use of PTA as a primary treatment for CLI has been increasing.[4] The lower morbidity and cost and results comparable to those of bypass surgery also support the increasingly significant role of PTA for CLI.[5]

Moreover, an increasing number of multisegment and more complicated arterial lesions are currently treated by angioplasty in patients with CLI.[4] Although many reports have demonstrated the effectiveness of PTA on CLI applied to each arterial segment, including the iliac,[6] femoropopliteal,[7] and tibial arteries,[8,9] not as many reports[4,10-14] have supported the general effectiveness of angioplasty on patients with CLI, and this has yet to be determined. Additionally, to our knowledge, few data have been published regarding long-term results, limited to 3 or 4 years, of PTA for CLI, which includes all anatomic lesions in the lower extremity.[11,12] The purpose of this study was to evaluate the total effectiveness of PTA in patients with CLI and the short- and long-term outcomes in terms of feasibility, safety, patency, clinical improvement, and limb salvage.

METHODS

Patient population. From August 1993 to March 2004, 138 limbs in 111 patients with CLI were treated

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by PTA at the University of California, Los Angeles, by a single vascular surgeon. All patients were primary cases. Patients who underwent a concomitant aortoiliac or infrainguinal open bypass operation on the same day or within 30 days before PTA were excluded from this study. Patients who were treated with a covered stent (three limbs) were not included. During the same period, 128 limbs underwent open operations (76 limbs with CLI and 48 limbs with claudication) without attempts at angioplasty or in combination with angioplasty. Sixty-four limbs underwent angioplasty with or without stent placement for claudication, and nine limbs underwent combined surgery (endovascular plus open surgery). Above-ankle amputations were performed in two patients without attempts at either PTA or bypass surgery.

All patients with CLI were treated with the same protocol. In patients with multiple lesions, ie, severe proximal (iliac, femoropopliteal, or both) lesions and mild or moderate distal (femoropopliteal, tibial, or both) lesions, proximal lesions were treated first without distal angioplasty; patients whose main lesions were distal (femoropopliteal, tibial, or both) arteries were treated with distal angioplasty with or without concomitant proximal angioplasty. In iliac lesions, stents were placed selectively for primary PTA failure, including residual stenosis (>30%), pressure gradient (>5 mm Hg), or both; stent placement was limited to patients with femoropopliteal occlusive lesions that did not respond to balloon dilation because of elastic recoil, arterial dissection, or both. No stent was placed in tibial lesions. Before-and-after pressures were routinely measured with papaverine injection in patients with iliac lesions and only when the patient had an angiographic problem, ie, residual stenosis, in patients with infrainguinal lesions. The criteria for open bypass surgery as the primary treatment for CLI were (1) bilateral common iliac artery occlusion, (2) unilateral external iliac occlusion, or (3) long (>10-cm) infrainguinal occlusion starting from the orifice of the superficial femoral artery (SFA). Long lesions with an open segment of proximal SFA were treated with PTA.

All patients had evidence of chronic CLI, defined as rest pain or ulcer/gangrene, and were included in a retrospective cohort study. Preoperative, intraoperative, and follow-up information was available for all patients; this information was obtained via office and hospital chart reviews and dictated operative records. The study protocol was approved by the local institutional review board.

PTA and stent technique. Angioplasty was performed in the operating room for all patients through an ipsilateral or contralateral femoral approach by using various sizes of introducer sheaths ranging from 5F to 9F (5F sheaths in 81 limbs [59%], 6F in 32 [23%], 7F in 23 [17%], 8F in 1 [0.7%], and 9F in 1 [0.7%]). Before intervention, arteriography was performed to quantify the extent of the disease in the operating room. Heparin sodium (100 IU/kg) was administered systemically. In tibial lesions, catheterization was made with "road mapping" of the arteries. Occlusions and stenoses were passed with a 0.014- to 0.035-inch guidewire. PTA was performed with standard angioplasty balloons (2-10 cm in length; 2-10 mm in diameter) selected to match the length of the lesion and the diameter of the artery. Pressure was 8 to 16 atm. Balloon inflation was repeated routinely two to four times at the same segment. If the primary angioplasty resulted in residual stenosis, angioplasty was repeated with a balloon 1 mm larger than the previous one. This protocol was applied prospectively to all patients. Patients were given aspirin before and after the procedure and were continued on aspirin thereafter. During the period of this study, the technique of PTA and stent placement did not change significantly. The indication of PTA for tibial lesions has been more aggressive recently, ie, for more distal or diffuse lesions and total occlusions.

Hemodynamic and radiologic evaluation. Ankle-brachial pressure index (ABI) measurements and duplex

Table I. Characteristics of the subjects treated with angioplasty for critical limb ischemia (111 cases; mean age ± SD, 70.9 ± 11.5 years)

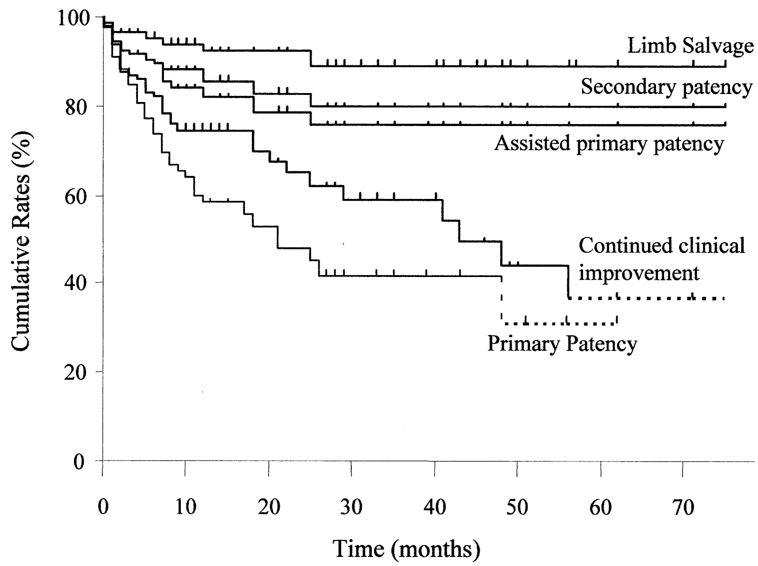
Variable	*n*	%
Male	64	58%
Female	47	42%
Coronary artery disease	67	58%
Diabetes mellitus	67	58%
Hypertension	64	57%
Smoking	44	40%
Hyperlipidemia	37	33%
Chronic renal failure with hemodialysis	22	20%
Cerebrovascular disease	14	13%
Chronic obstructive lung disease	6	5%

Table II. Characteristics of the limbs treated with angioplasty for critical limb ischemia: 138 limbs

Variable	*n*	%
Indication for PTA		
Ischemic rest pain	62	45%
Ulcer/gangrene	76	55%
No. of segments treated*		
1	76	55%
2	60	43%
3	2	2%
The most distal artery treated		
Iliac artery (iliac group)	45	33%
Femoropopliteal artery (FP group)	41	30%
Tibial arteries (BK group)	52	37%
TASC classification for the lower limb		
Type A	0	
Type B	13	9%
Type C	74	54%
Type D	51	37%

PTA, Percutaneous transluminal angioplasty; *TASC,* TransAtlantic Inter-Society Consensus.

*Iliac, femoropopliteal, and/or tibial segments.



Limb salvage

At risk	138	52	36	22	17	8	4	3
S.E.	.000	.022	.029	.040	.040	.040	.040	.040

Continued clinical improvement

At risk	138	41	28	17	13	7	4	3
S.E.	.000	.043	.056	.067	.067	.090	.010	.010

Secondary patency

At risk	138	44	28	16	13	7	4	3
S.E.	.000	.032	.046	.055	.055	.055	.055	.055

Assisted primary patency

At risk	138	42	27	15	12	7	4	3
S.E.	.000	.038	.050	.057	.057	.057	.057	.057

Primary patency

At risk	138	38	20	9	6	3	1
S.E.	.000	.051	.061	.069	.069	.010	.010

Fig 1. Kaplan-Meier life-table analysis of outcomes after angioplasty for critical limb ischemia in 138 limbs. *Dashed line*, Portion of plot where the SE is greater than 10%.

Table III. Outcomes of the limbs treated with angioplasty for critical limb ischemia in each subgroup (Kaplan-Meier life-table analysis)

Group	*n*	*Time interval (mo)*	*Primary patency*	*Assisted primary patency*	*Secondary patency*	*Continued clinical improvement*	*Limb salvage*
All patients	138	60	31.4% ± 10.4%	75.5% ± 5.7%	79.6% ± 5.5%	36.1% ± 10.0%	89.1% ± 4.0%
Iliac group	45	36	51.6% ± 11.0%	94.7% ± 3.6%	97.8% ± 2.1%	65.1% ± 10.1%	95.0% ± 4.8%
FP group	41	36	49.4% ± 11.9%	72.2% ± 9.8%	76.4% ± 9.1%	57.4% ± 13.5%	92.7% ± 4.0%
BK group	52	36	23.5% ± 10.7%	41.8% ± 16.4%	46.1% ± 17.6%	51.1% ± 12.5%	77.3% ± 11.5%

scans were obtained before treatment. Doppler ultrasound waveforms were also evaluated in limbs with falsely increased ankle pressures caused by severe arterial calcification. Patients were usually seen within 2 weeks after the procedure. Postoperative follow-up (clinical examination, ABI measurements, and serial duplex ultrasound scanning) was conducted every 3 months during the first postoperative year and every 6 months thereafter. Indications for repeat intervention included recurrent symptoms accompanied by a less than 0.10 increase in ABI or recurrent stenosis

Table IV. Variables tested for outcomes after angioplasty in patients with critical limb ischemia: 138 limbs.

Variable	No.	Primary patency: Failure rate per 100 person-months	Primary patency: Rate ratio	Primary patency: P	Assisted primary patency: Failure rate per 100 person-months	Assisted primary patency: Rate ratio	Assisted primary patency: P
Gender							
Male	80	3.234	0.78	.51	1.1	0.99	.83
Female	58	4.141	1		1.106	1	
Age							
< 70	68	3.647	1	.62	1.14	1	.45
70 or > 70	70	3.499	0.96		1.05	0.92	
Smoking							
Yes	56	3.491	0.96	.68	0.813	0.64	.24
No	82	3.641	1		1.278	1	
Coronary artery disease							
Yes	88	3.522	0.96	.84	1.248	1.5	.44
No	50	3.688	1		0.847	1	
Hypertension							
Yes	88	4.955	2.44	.024	0.846	1	.53
No	50	2.034	1		1.3	1.5	
Diabetes mellitus							
Yes	84	4.229	1.56	.14	1.275	1.6	.27
No	54	2.677	1		0.817	1	
Hyperlipidemia							
Yes	51	2.767	0.67	.27	0.806	0.63	.32
No	87	4.133	1		1.285	1	
Chronic renal failure with hemodialysis							
Yes	27	2.869	0.76	.62	1.19	1.09	.90
No	111	3.755	1		1.087	1	
Indication for PTA							
Rest pain	62	3.333	0.87	.24	0.848	0.58	.40
Ulcer/gangrene	76	3.834	1		1.415	1	
No. of segments treated*							
1	76	2.486	1	.0083	0.571	1	.028
2/3	62	7.095	2.85		0.85	4.7	
The most distal artery treated							
Iliac group	45	2.054	0.28	.0077	0.117	0.03	.0026
FP group	41	3.723	0.51		1.59	0.48	
BK group	52	7.287	1		3.309	1	
TASC classification							
B	13	0.909	1	.0158	0		.0015
C	74	2.789	3.1		0.466	N/A	
D	51	5.852	6.4		2.908		

Kaplan-Meier, log-rank test.
PTA, Percutaneous transluminal angioplasty; *TASC,* TransAtlantic Inter-Society Consensus.
*Iliac, femoropopliteal, and/or tibial segments.

greater than 60% by duplex scan (a threefold difference of the velocity across the lesion is estimated as a 60%-80% stenosis by our institute's vascular laboratory). Patients with insufficient vascular laboratory records were considered lost to follow-up in patency analysis.

Data analysis. The occlusive lesions in the lower extremity were classified by angiographic findings according to TransAtlantic Inter-Society Consensus (TASC).[15] The procedure on the most distal arterial segment (iliac, femoropopliteal, or tibial) of one limb in each patient was evaluated. Demographic information, risk factors, and all independent variables were statistically analyzed and correlated with outcome. Success of PTA was defined anatomically, hemodynamically, and clinically according to the Society for Vascular Surgery and the International Society for Cardiovascular Surgery reporting standards[16,17]: (1) PTA was deemed technically successful if there was less than 30% residual stenosis and, in iliac lesions, the brachiofemoral pressure gradient was less than 5 mm Hg; (2) PTA was considered as a clinical success/improvement if the symptoms improved by at least one category together with an increase in ABI of more than 0.10 (this constitutes primary clinical success instead of continued or corrected clinical success after successful reintervention); (3) patency was determined by duplex scans, ABI measurements, or both; (4) all revisions performed on the basis of the criteria described previously or occlusion at any lesion on the same limb were considered primary PTA failures; and (5) all analysis was performed on an intent-to-treat basis, including initial technical failures.

Statistical analysis. The Kaplan-Meier method (KM) was used to determine the outcome at sequential intervals.

Table IV. Continued.

Secondary patency			*Continued clinical improvement*			*Limb salvage*		
Failure rate per 100 person-months	*Rate ratio*	*P*	*Failure rate per 100 person-months*	*Rate ratio*	*P*	*Failure rate per 100 person-months*	*Rate ratio*	P
1.087	1.4	.73	2.071	0.9	.29	0.435	0.9	.85
0.793	1		2.411	1		0.469	1	
0.891	1	.77	1.599	1	.27	0.505	1	.37
1.049	1.2		3.201	2		0.369	0.7	
0.806	0.8	.45	2.247	1.02	.93	0.606	1.6	.72
1.041	1		2.19	1		0.373	1	
1.012	1.2	.70	2.172	0.95	.84	0.377	0.6	.59
0.847	1		2.28	1		0.592	1	
1.033	1.2	.84	2.346	1.2	.84	0.342	0.6	.30
0.846	1		2.011	1		0.602	1	
1.133	1.8	.24	2.309	1.1	.61	0.444	0.96	.81
0.647	1		2.024	1		0.461	1	
0.64	0.6	.26	1.463	0.6	.14	0.288	0.5	.37
1.141	1		2.627	1		0.536	1	
0.76	0.8	.54	3.731	1.9	.18	0.612	1.5	.81
0.99	1		1.93	1		0.418	1	
0.848	0.8	.86	1.386	0.4	.064	0.281	0.4	.31
1.09	1		3.385	1		0.641	1	
0.475	1	.023	1.726	1	.21	0.215	1	.083
2.381	5		3.419	1.9		0.873	4	
0.116	0.04	.0104	1.527	0.5	.62	0.117	0.1	.20
1.304	0.5		2.49	0.8		0.465	0.5	
2.878	1		0.83	1		1.002	1	
0		.0098	0.645	1	.053	0		.0034
0.463	N/A		1.661	2.6		0.085	N/A	
2.263			3.958	6.1		1.203		

Differences between subgroups were determined with the univariate log-rank test and multivariate Cox regression model. Statistical significance was defined as a *P* value $<.05$.

RESULTS

Demographic information. The clinical characteristics of 111 patients are summarized in Tables I and II. There were 64 men (58%) and 47 (42%) women, with a mean age of 7.09 years (range, 45-98 years). Twenty-seven patients (24%) were older than 80 years during the time of the initial procedure. Fourteen limbs (10%) were noted to have falsely increased ankle pressure (>250 mm Hg). In the remaining limbs, the mean ABI was 0.4 (range, 0.19-0.89) before intervention. Indications for PTA were ischemic rest pain in 62 limbs (45%) and ulcer/gangrene in 76 limbs (55%). The most distal affected arteries treated with angioplasty were the common and/or external iliac artery in 45 limbs (33%; iliac group), the femoral (common, superficial, and/or deep femoral) and/or popliteal artery in 41 (30%; FP group), and the tibial arteries in 52 (37%; BK group). In the iliac group, 14 limbs (28%) underwent the selective placement of 1 to 3 stents (20 stents in total). In the FP group, 16 limbs (39%) underwent concomitant iliac PTA, whereas PTA was performed in the femoropopliteal segments alone on 25 limbs (61%). In the BK group, concomitant proximal angioplasty was performed on 42 limbs (81%)—in the SFA on 12 (23%), in the popliteal artery on 6 (12%), and in the femoropopliteal segment on 24 (46%)—whereas only tibial arteries were treated with PTA on 10 (19%). Subintimal angioplasty was performed in most of the totally occluded lesions treated (1 iliac, 8 superficial femoral, 12 popliteal, and 6 tibial arteries). Only two limbs (2.4%) underwent stent placement in the femoral and/or popliteal arteries.

Initial success and early complications. The average hospital stay was 3.2 days (range, 0-30 days). In 138 limbs, initial technical success was obtained in 133 limbs (96.4%), and initial clinical success was obtained in 128 limbs (92.8%). Procedural mortality, defined as death within 30 days after the procedures, was 1 (0.9%) in 111. Five limbs (3.6%) underwent above-ankle amputation within 30 days. Groin and/or flank hematoma that required evacuation occurred in three patients (2.2%). There was no other major complication.

Long-term success. The mean follow-up was 14.7 months (range, 1-75 months). Eighteen patients (13%) were lost to follow-up. Primary PTAs were followed by subsequent open bypass surgery in 13 limbs (9.4%; 5 popliteal, 6 tibial, and 2 pedal bypass operations) for the purpose of limb salvage: 6 limbs in the iliac group, 4 limbs in the FP group, and 3 limbs in the BK group. A total of nine limbs (6.5%), including the five within 30 days after PTA, underwent above-ankle amputation (eight below the knee and one above the knee). Of these nine limbs, no distal bypass surgery was attempted because of unreconstructable distal vessels and advanced gangrene and/or infection, except for one that underwent subsequent external iliac-to-popliteal bypass in the iliac group. Six of the patients with amputated limbs had diabetes, and the indications for the initial PTA were gangrene in six limbs and rest pain in three limbs.

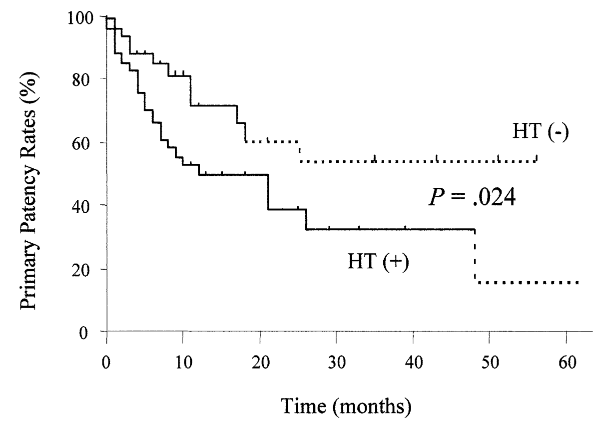
Over all, the cumulative primary patency, assisted primary patency, secondary patency, continued clinical improvement, and limb salvage rates ± SE at 5 years were 31.4% ± 10.4%, 75.5% ± 5.7%, 79.6% ± 5.5%, 36.1% ± 10.0%, and 89.1% ± 4.0%, respectively (Fig 1 and Table III). The results for the iliac, FP, and BK groups at 36 months are presented in Table III.

Univariate analysis of risk factors. Of the 12 predictable variables studied in 138 limbs, 4 were significant (Table IV). Primary patency was significantly decreased for hypertensive patients (KM; log-rank test; $P = .027$; Fig 2). Both multiple-segment lesions and more distal lesions significantly decreased primary, assisted primary, and secondary patency rates (KM; log-rank test; $P < .05$; Figs 3 and 4). Patients with TASC type D had significantly decreased primary, assisted primary, secondary patency, and limb salvage rates (KM; log-rank test; $P < .05$; Fig 5). There was a trend that ulcer/gangrene ($P = .064$) and TASC type D ($P = .053$) decreased continued clinical improvement (Table IV).

Multivariate analysis of risk factors. Multiple regression analysis revealed that hypertension, the number of segments treated, the most distal segments treated, and TASC classification were significant independent risk factors ($P < .05$; Table V).

DISCUSSION

The role of PTA for CLI is still controversial. However, the clinical advantages of PTA are well established for the high-risk, elderly, and vascularly compromised patient: there is no need for general or spinal anesthesia, there are no or fewer surgical wounds, the hospital stay is shorter, and complication and mortality rates are



HT (-)							
At risk	50	18	11	5	4	3	
S.E.	.000	.065	.10	.11	.11	.11	
HT (+)							
At risk	88	20	9	4	2	2	1
S.E.	.000	.067	.072	.094	.094	.12	.12

Fig 2. Kaplan-Meier life-table analysis (log-rank test) of primary patency rates. Hypertensive *[HT (+)]* patients had significantly decreased primary patency rates compared with nonhypertensive *[HT (−)]* patients. *Dashed line*, Portion of plot where the SE is greater than 10%.

low.[13,18] The angiographic evaluation in the operating room on the same day of endovascular procedures reduces both patient stress and the amount of contrast administered: these are particularly relevant in patients with cardiovascular diseases or nephropathy.[19] For all these reasons, we have been considering PTA as a first-line procedure in patients with CLI whenever possible and have not limited the indication for PTA to patients who cannot undergo an operation. Bypass surgery has been considered a second-line procedure after PTA failure except for patients with the criteria mentioned previously. We considered it clinically important to review the outcome of PTA for all patients with CLI because it may dictate the best treatment for those subjects.

This study revealed a high technical success rate (96%), a high initial clinical success rate (93%), and a low complication rate (2%). These results are in agreement with other reports.[4,8,12] The overall procedure-related serious complication rate within 30 days after angioplasty for CLI, including death, acute renal failure, and limb loss, was less than 1% in this series.

However, the primary patency rate was low in this study: 31.4% at 5 years. Compared with patients with intermittent claudication, patients with CLI seem to have much higher re-stenosis rates.[10] This result might reflect the characteristic factors of our CLI population. In this study, 58% were diabetic, 24% were older than 80 years of age, 20% had chronic renal failure and hemodialysis, and all but one who underwent major amputations had unreconstructable distal vessels and advanced gangrene, infection, or both. Inclusion of these patients probably had a negative effect on the results of PTA.

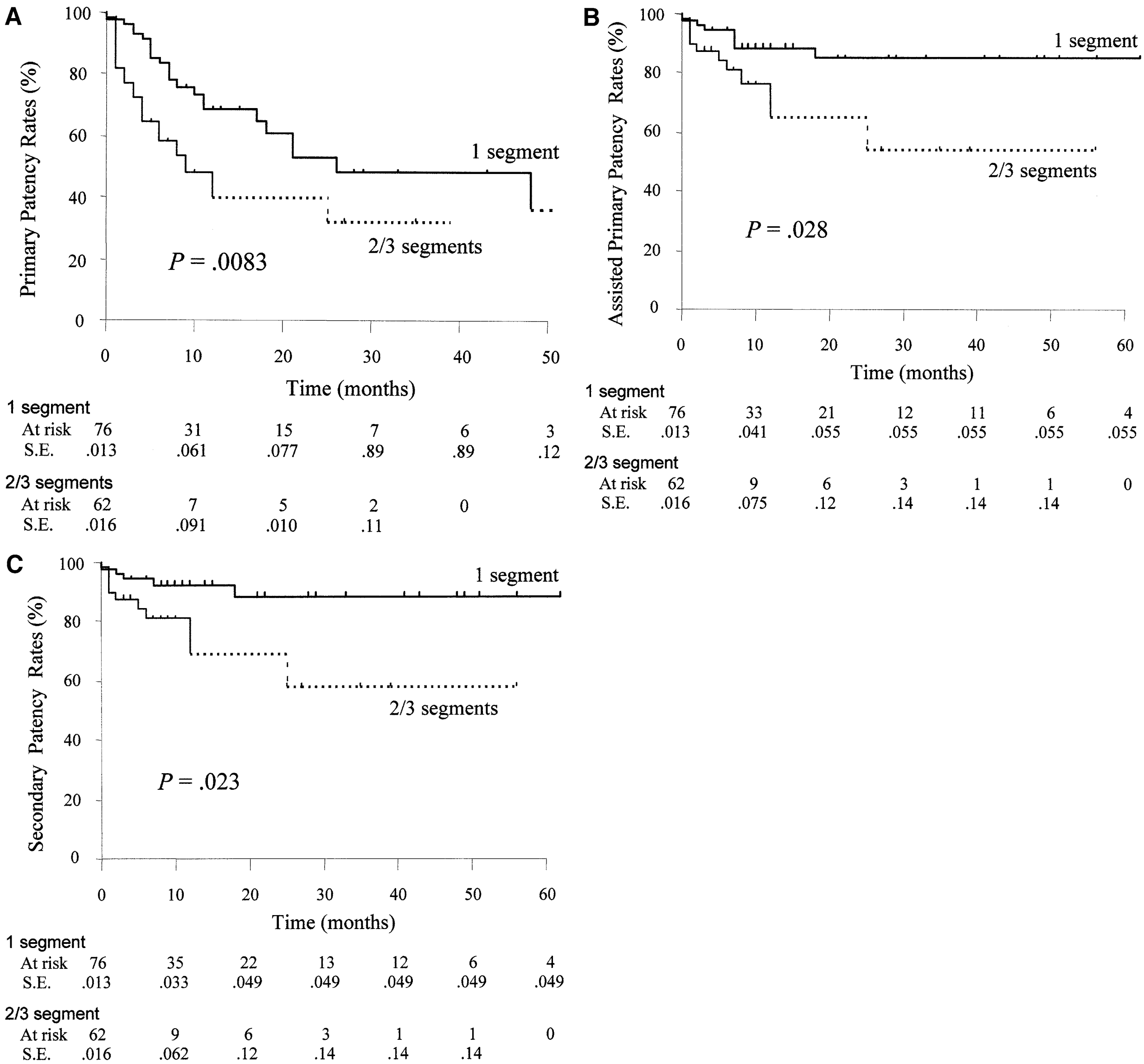
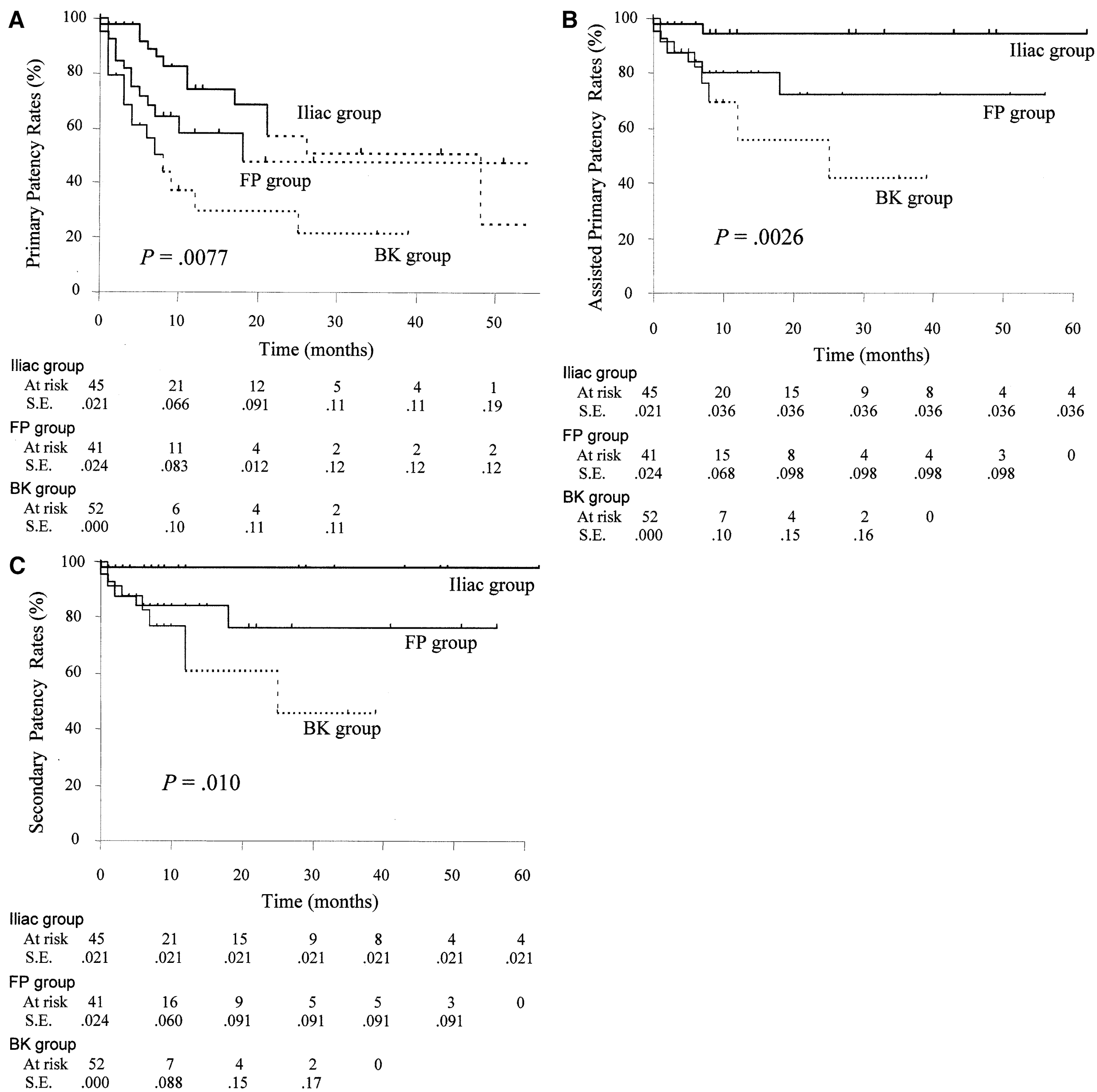


Fig 3. Kaplan-Meier life-table analysis in patients with one and two or three segments treated. **A,** Primary patency rates. **B,** Assisted primary patency rates. **C,** Secondary patency rates. *Dashed line*, Portion of plot where the SE is greater than 10%.

Because of the poor patency rates, angioplasty is often not considered as a primary treatment modality for CLI.[3] However, clinical improvement and avoidance of major amputation are more crucial elements when assessing the efficacy of any therapeutic approach for CLI. In our experience, the clinical recurrence rate was not high; primary continued clinical improvement was maintained in 74% of limbs at 1 year and in 58% at 3 years. This result is higher than the primary patency rate described in previous reports.[8] Additionally, the above-the-ankle amputation rates in our series were low. In patients with unreconstructed CLI, a 54% limb salvage rate at 1 year has been reported.[20] Our short-term limb salvage rate (92% at 1 year) was much higher than that, which was in agreement with previous reports: 88% at 12 months[4] and 80% at 18 months.[8] Our long-term limb salvage rate was still high: 89% at 6 years. As the site of PTA moves more distally in the arterial tree, the benefits have been considered less clear.[3] However, stratified analysis in our study revealed that each subgroup showed a good limb salvage rate in our series. These results support the argument that PTA is a rational treatment option for all CLI.

The reason for better primary continued clinical improvement and limb salvage rates compared with primary patency rates might be explained as follows. (1) Extra perfusion is necessary to heal the tissue loss, but once it heals, the skin



A

Iliac group						
At risk	45	21	12	5	4	1
S.E.	.021	.066	.091	.11	.11	.19
FP group						
At risk	41	11	4	2	2	2
S.E.	.024	.083	.012	.12	.12	.12
BK group						
At risk	52	6	4	2		
S.E.	.000	.10	.11	.11		

B

Iliac group							
At risk	45	20	15	9	8	4	4
S.E.	.021	.036	.036	.036	.036	.036	.036
FP group							
At risk	41	15	8	4	4	3	0
S.E.	.024	.068	.098	.098	.098	.098	
BK group							
At risk	52	7	4	2	0		
S.E.	.000	.10	.15	.16			

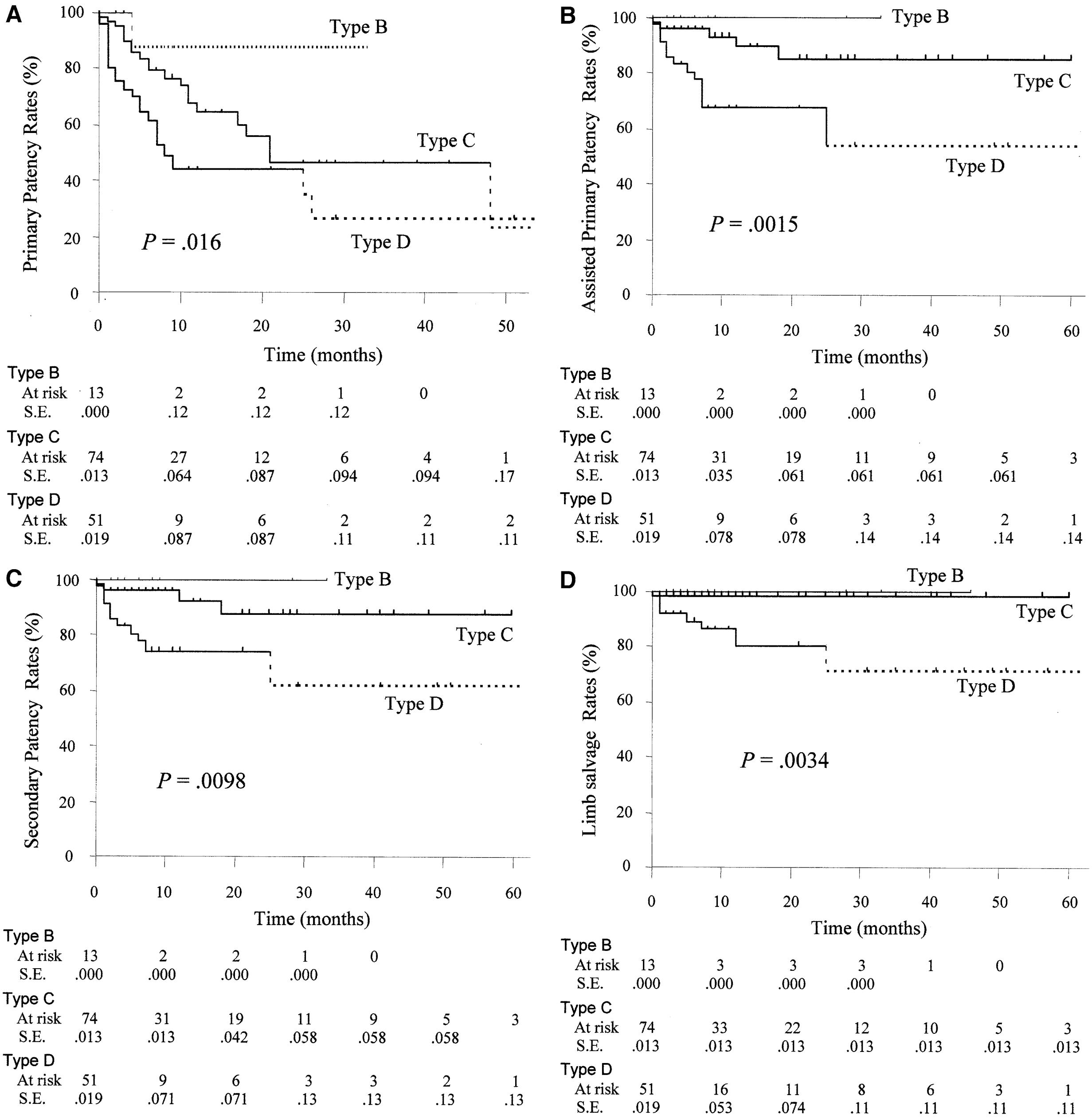
C

Iliac group							
At risk	45	21	15	9	8	4	4
S.E.	.021	.021	.021	.021	.021	.021	.021
FP group							
At risk	41	16	9	5	5	3	0
S.E.	.024	.060	.091	.091	.091	.091	
BK group							
At risk	52	7	4	2	0		
S.E.	.000	.088	.15	.17			

Fig 4. Kaplan-Meier life-table analysis in the iliac, patients with the most distal affected arteries treated with PTA were the common or external iliac artery; FP, patients with the most distal affected arteries treated with PTA were the femoral (common, superficial, or deep femoral) or popliteal artery; and BK, patients with the most distal affected arteries treated with PTA were the tibial arteries groups. **A,** Primary patency rates. **B,** Assisted primary patency rates. **C,** Secondary patency rates. *Dashed line*, Portion of the plot where the SE is greater than 10%. *PTA*, Percutaneous transluminal angioplasty.

viability can be maintained even though the treated artery re-occluded;[11] and (2) slow re-stenosis of the treated artery allows time to form new collateral circulation. When no pain is present or tissue healing has occurred in CLI patients, a possible delayed closure of the recanalized vessel may not always be clinically relevant.[13] This is similar to the limb that remained intact after the original bypass thrombosed.[21]

Some shortcomings of this study, such as the bypass cases and those lost to follow-up, might have partially contributed to the high limb salvage rate. Thus, we re-evaluated the limb salvage rate by excluding the 13 bypass cases but still found a similar limb salvage rate (87.3% ± 4.8%) at 5 years. When we excluded the patients who were lost to follow-up (18 limbs), the primary, assisted primary, secondary, continued clinical improvement, and limb salvage rates ± SE at 5 years were 29.9% ± 10.1%, 75.7% ± 6.0%, 78.8% ± 5.7%, 34.4% ± 9.6%, and 88.2% ± 4.2%, respectively. These results are similar to our previously



A

		0	10	20	30	40	50
Type B	At risk	13	2	2	1	0	
	S.E.	.000	.12	.12	.12		
Type C	At risk	74	27	12	6	4	1
	S.E.	.013	.064	.087	.094	.094	.17
Type D	At risk	51	9	6	2	2	2
	S.E.	.019	.087	.087	.11	.11	.11

B

		0	10	20	30	40	50	60
Type B	At risk	13	2	2	1	0		
	S.E.	.000	.000	.000	.000			
Type C	At risk	74	31	19	11	9	5	3
	S.E.	.013	.035	.061	.061	.061	.061	
Type D	At risk	51	9	6	3	3	2	1
	S.E.	.019	.078	.078	.14	.14	.14	.14

C

		0	10	20	30	40	50	60
Type B	At risk	13	2	2	1	0		
	S.E.	.000	.000	.000	.000			
Type C	At risk	74	31	19	11	9	5	3
	S.E.	.013	.013	.042	.058	.058	.058	
Type D	At risk	51	9	6	3	3	2	1
	S.E.	.019	.071	.071	.13	.13	.13	.13

D

		0	10	20	30	40	50	60
Type B	At risk	13	3	3	3	1	0	
	S.E.	.000	.000	.000	.000			
Type C	At risk	74	33	22	12	10	5	3
	S.E.	.013	.013	.013	.013	.013	.013	.013
Type D	At risk	51	16	11	8	6	3	1
	S.E.	.019	.053	.074	.11	.11	.11	.11

Fig 5. Kaplan-Meier life-table analysis in TransAtlantic Inter-Society Consensus types B, C, and D. **A,** Primary patency rates. **B,** Assisted primary patency rates. **C,** Secondary patency rates. **D,** Limb salvage rates. *Dashed line,* Portion of the plot where the SE is greater than 10%.

calculated results, which included both the bypass patients and those lost to follow-up. Thus, we believe that repeat angioplasty plays a significant role, because our assisted primary (75.5% at 5 years) and secondary (79.6% at 5 years) patency rates were excellent and similar to our limb salvage rate. The mean follow-up (14.7 months) was short, because (1) 40.6% of limbs (56/138) were treated in the last 2 years during the study period; (2) the mortality rate was high (56% at 5 years) in the population; and (3) 18 limbs (13%) were lost to follow-up.

Although PTA seems to allow satisfactory continued clinical improvement and limb salvage, its effectiveness as the primary procedure in patients with CLI in comparison with conventional bypass surgery has not been determined. One prospective study with severe lower limb ischemia reported that PTA and bypass surgery achieved the same limb salvage rate of 76% at 1 year.[22] Another recent prospective study demonstrated that angioplasty can be used in the management of CLI without compromising limb salvage, patient survival, and subsequent vascular interven-

Table V. Multivariate analysis: risk factors for adverse outcomes (multivariate Cox regression model)

Variable	*Hazard ratio*	*95% Hazard ratio confidence limits*		*P value*
Primary patency				
Hypertension	2.673	1.336	5.346	.0054
The most distal artery treated	0.387	0.198	0.758	.0056
TASC D vs TASC B + C	2.542	1.394	4.636	.0023
Assisted primary patency				
The most distal artery treated	0.139	0.032	0.608	.0088
TASC D vs TASC B + C	4.84	1.825	12.835	.0015
Secondary patency				
The most distal artery treated	0.087	0.011	0.665	.0186
TASC D vs TASC B + C	4.596	1.591	13.276	.0048
Continued clinical improvement				
Age (per year)	1.026	0.996	1.057	.0949
Indication for PTA	0.493	0.252	0.965	.0389
TASC D vs TASC B + C	2.26	1.179	4.331	.0140

TASC, TransAtlantic Inter-Society Consensus; *PTA,* percutaneous transluminal angioplasty.

tion, in comparison to bypass surgery.[23] In our experience, the 5-year limb salvage rate was 89%, which is comparable to those reported previously in the series of patients with bypass surgery: a 5-year rate of 70% to 80%.[24] Additionally, several previous studies have shown that failure of angioplasty did not preclude the possibility of performing subsequent bypass grafting.[4] In a previous study of tibial PTA in diabetic patients with ischemic foot ulcers, clinical recurrence was well managed by a second PTA.[11] These studies also support that PTA can be the first-line treatment for CLI patients even though they are not poor surgical candidates. Finally, CLI is a manifestation of a diffuse, severe form of arteriosclerosis, which is reflected in the high death rates of previous reports: 20% to 27% at 1 year,[10,25] 31.6% at 2 years,[26] and more than 60% at 5 years.[27] The 5-year mortality rate was 56% in this study. These data suggest that a clinical benefit (symptomatic improvement and limb salvage) and defect (complication) from a treatment procedure might be more essential than long-term patency for patients with severe CLI symptoms, including ulcers and gangrene, as well as rest pain.

We studied the effects of 12 predictable variables on patency, continued clinical improvement, and limb salvage. The univariate log-rank test and multivariate analysis revealed that four independent factors might affect PTA outcome: hypertension, the number of segments treated, the most distal segments treated, and TASC classification. All factors likely reflected a severe systemic and peripheral extent of arteriosclerosis, which would be associated with poor outcome. However, it is not appropriate to conclude that PTA is not worthwhile for this subgroup. Even though (1) the BK group had the most predisposing risk factors (approximately 60% were diabetic, almost a third had chronic renal failure and hemodialysis, and almost a third were older than 80 years of age) and (2) all patients with amputations in the BK group had unreconstructable distal vessels, they still had a reasonable limb salvage rate, and endovascular procedures might be the only alternative to amputation.

Judging the outcome of PTA as successful requires objective and uniform criteria.[17] We believe that the combination of clinical examination and suitable noninvasive diagnostic modalities, such as duplex ultrasonography, might offer better follow-up evaluation after angioplasty. It might also be useful for detection of re-stenosis and could contribute to better assisted primary and secondary patency rates.

In conclusion, PTA is a feasible, safe, and effective procedure for the treatment of CLI. Initial technical and clinical success rates were high, and procedural mortality and complication rates were low. In long-term results, our data demonstrated a 76% assisted primary rate, an 80% secondary patency rate, and an 89% limb salvage rate at 5 years: the high limb salvage rate was attributed to the high assisted primary and secondary patency rates despite the low primary patency rate. Because the purpose of treatment in this population is limb salvage and symptom relief (rather than long-term primary patency), PTA can be the primary choice for the management of CLI. Our risk factor analysis indicated that hypertension, multiple segment lesions, more distal lesions, and TASC type D were significant independent predictors of worse long-term results.

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DISCUSSION

Dr Timothy Liem (Portland, Ore). I would like to congratulate Drs Chandra, Kudo, and Ahn for their large series of patients, which is especially notable since all the patients were treated by a single vascular surgeon over a 10½-year period. I would also like to thank the authors for timely submission of their manuscript.

The authors have demonstrated that in a select group of patients with limb-threatening ischemia, percutaneous angioplasty is a reasonable first option. I would agree with their practice of offering percutaneous interventions not only to poor-surgical-risk but also acceptable-surgical-risk patients. Ms Chandra has shown us today that just as in open bypass surgery, the limb salvage rates can be very acceptable, in the range of 77% to 89%, even when the primary patency is significantly lower. In addition, the literature has shown that patients with limb-threatening ischemia in general have a fairly poor overall rate of survival, in the range of 50% at 3 or 5 years. As the authors stated, long-term primary patency may not be as crucial in patients with such a limited life expectancy. My first question relates to this: what was their 3- or 5-year survival in this series of patients?

I also have a word of caution regarding one conclusion from their manuscript stating that percutaneous angioplasty was feasible in most patients with limb-threatening ischemia. I am not sure that can be substantiated with these data.

The patients in this series were a fairly select group. Those patients who had occlusions longer than 10 cm below the groin and those who subsequently underwent open bypass within 30 days after percutaneous angioplasty were excluded. Many, if not most, patients who present with limb-threatening ischemia will have longer than 10 cm of arterial occlusion. Therefore, percutaneous angioplasty should certainly be in the armamentarium of a vascular surgeon sometimes to be used as a sole treatment modality in patients with shorter segment stenosis or occlusion. However, my guess is that we will still use it more commonly in conjunction with open surgical bypass for patients with critical limb ischemia.

I have a few more questions for the authors. They used stents only selectively in the iliac arteries and not at all in the infrainguinal arteries. Do the authors foresee a greater role for stents, primarily primary stenting, in the future?

Second, what role is there for subintimal angioplasty, with or without stenting?

Third, the authors used heparin around the time of the procedure and aspirin afterward. Are the authors using any other medications, such as clopidogrel, before or after the angioplasty?

Finally, I have an additional question. There was a noted decreased clinical improvement rate when compared with the limb salvage rate. Is this due to the reporting standards requiring the ABI to still be significantly improved over that long-term period?

Again, I'd like to thank the authors for their presentation and manuscript.

Dr Ahn. Thank you very much for those questions and your thoughtful analysis. Ms Chandra is perfectly capable of answering them, but I thought you might want to hear from the responsible surgeon directly. Also, I might add that Ms Chandra is actually an undergraduate student at UCLA. As you can see, she did a fine job on presenting a very complicated medical problem.

In answer to the questions, the 3- and 5-year survival rates in this series were 64% and 44%. As far as your comments about excluding patients from the series and its being highly selective, I think you said that we excluded patients after PTA, and that is an inaccurate comment. We excluded patients who had open surgery before any PTA, and those were the 58 patients who we mentioned were excluded. Those 58 patients were the ones who had an open procedure either with or without PTA subsequently, and therefore those were excluded so as not to contaminate the pure PTAs. Any patients who had PTA or open surgery or stents after my initial PTA were part of the study group, which numbered 111 in total. Thus, you can see I excluded about a third of the patients (58 vs 111). That means two thirds of the patients had primary PTA as the indication for the procedure. I must also say that earlier in the series I was more inclined to do open surgery than PTA. In the past year or two, I probably do a primary open procedure in only 10% to 20% of the patients that I see with limb-threatening ischemia.

You asked some questions about the role of primary stenting in the future. I think there is probably an increased role of primary stenting in the external iliacs, and also I think there is an increased role of cover stent grafts, ie, the Viabahn grafts, among others, in the SFA and especially in patients who have long total occlusions. There are very few long total occlusions that I cannot treat with subintimal dissection plus or minus a cover stent graft.

Do I use any other medications now? Yes. Early in the series it was only aspirin. In the past at least 1 year, I have added Plavix routinely to these patients after surgery. Oh, by the way, when they come back for reintervention, I keep them on the Plavix indefinitely. I do not stop the Plavix at all.

Regarding the decreased clinical success rate, if you go back to the original reporting standards article, the strict definition of clinical success is primary clinical success. There is no word or verbiage in that document to account for secondary or continued clinical success. Thus, the clinical success rate follows the curves of the primary patency and not the assisted primary patency, secondary patency, or limb salvage rates.

Dr Ronald Dalman (Stanford, Calif). I have a question, Sam. On this cohort you get a 93% limb salvage for femoropopliteal interventions at a 5-year mean follow-up and 77% for below-knee interventions, and that just seems extraordinarily good compared with open surgery, so part of the issue is, I guess, that we do not know what the survival is, so maybe a lot of patients are dying early at various times, and then the other point that Tim brought up was that part of the patients, if they require bypass surgery within 30 days of the procedure, they are falling out too.

Dr Ahn. No, no, that is not true.

Dr Dalman. Help me understand. . .

Dr Ahn. If they required bypass surgery within 30 days or any time after the PTA, that counted as a failure.

Dr Dalman. Okay, so do you have any comment about a 77% limb salvage rate for below-knee catheter-based intervention at 5-year follow-up? Or is that just what it is?

Dr Ahn. I think that there are several explanations for that. Number one is what you pointed out and Tim pointed out. It could be a factor of the survival. Those patients with below-knee infrainguinal disease tend to be your diabetic chronic renal failure patients who do not live more than 2 to 4 years, and they may drop out and die, but they die with their limbs intact. The other is that the gangrene and tissue loss only needs to heal, and once they heal, it probably doesn't matter whether your angioplasty site goes down or not because it takes a lot more to heal an ulcer and gangrene than to maintain a healed gangrene. Also, during that time after angioplasty, if they do re-stenose, they may have time to develop more collaterals during that gradual re-stenosis. And then finally, I think there is a factor of good surveillance, and I know several members here in this audience have talked about the importance of surveillance. Our primary assisted patency and our secondary patency are almost as good as our limb salvage, and that is because of good surveillance. Our primary patencies are awful, but we follow up our patients carefully, we intervene when there is still a failing rather than a failed angioplasty site, and we intervene and get a really good primary assisted patency and a really good secondary patency, and that is reflected in our more favorable limb salvage.

Dr James Watson (Seattle, Wash). I also would like to congratulate Ms Chandra on an excellent presentation. I was struck by your 25% primary patency of iliac interventions at 5 years. That seems low to me. It is unclear what percentage of those were just angioplasties and what percentage were stents. Has that changed your practice, because most of the time now I don't perform bare iliac angioplasty without stent placement. Twenty-five percent seems low. Has that changed your practice at all?

Dr Ahn. Yes. I think that low primary patency is reflected by my aversion to use stents and also partly that these angioplasties do need reintervention frequently, and I think our data point that out, but as you can see, our secondary and primary assisted patencies were superb. Again, it points back to the need for good surveillance. I am more inclined now to use a primary stent for external iliacs, as well as for re-stenosis, and hopefully my results 10 years from now will reflect some improvement.

Dr George Andros (Los Angeles, Calif). First of all, you are on a very slippery slope when you give us limb-threatening ischemia. That is probably one of the most difficult subjects we deal with now, and for myself I take the hard line. I think you have to give us really good data. I want ankle pressures. I want toe pressures. I want to know what the lesions looked like, and you just can't say "this is limb-threatening ischemia" and not characterize it to a fare-thee-well, so I think that is the first problem you have with this. I really want to know why these people, you think, are so ischemic.

My second question is, does this paper adhere to Andros' first two principles of endovascular therapy, the first being "the less you need it, the better it works"? So, are these people really as bad as you say? The second one is "get them healed." Now you said you just get them healed, and once they are healed, if the revascularization goes down they will stay healed, and that is entirely contrary to the data in the literature and my own personal experience. Fifty-eight percent of your patients were diabetics. Were these people really having rest pain? Diabetics don't get rest pain; they get neuropathy. So I would like to have that better characterized. Do you measure hemodynamic success intraprocedurally? For example, do you routinely do not just the cosmetic, the appearance of the lesion, but do you do before-and-after pressures with and without papaverine? I ask that because we are now locked in a mortal battle with the interventional radiologists and the cardiologists, and if we are going to play the game according to their rules (which is do the procedure, look at the result, and send a bill), we have to do better than that because if we are going to play the game the way they play it, we are going to lose, but if we can hold to our higher standards, I think we are going to be in a better position. Sorry for the editorial.

Dr Ahn. Thank you, George. I certainly agree with your comments that we need to follow up our patients very carefully and not just be technicians, and I think that is partly reflected in our good results, because first of all we do have good follow-up on these patients and good hemodynamic measurements, as well as just eyeball measurements. I think that is partly why we have such good secondary patencies, because we are able to intervene appropriately. I do measure intraoperative pressures for the iliacs routinely, but not for the SFA and tibials, because I don't know how to do that effectively, because when you put a catheter down into an SFA and tibial and you are measuring the pressure distal to your catheter and your catheter takes up 50% of the lumen, I don't know what that pressure drop means past the catheter.

Dr Andros. Do you use the pressure wire?

Dr Ahn. That is a good suggestion. I had not used the pressure wire. The cardiologists use that routinely, and it is also very expensive, I might add. I'm not sure our hospital would look favorably on that.

As far as characterization of the lesions, the tissue loss and gangrene are obvious. I mean I don't need to show you a picture of that. Everyone in the room knows what gangrene and tissue loss is. The ischemic rest pain is a little slippery slope, as you said, but these were all patients—if they had ischemic rest pain, I think I know after 20 years of practice, I think I know what ischemic rest pain is, and I'll now define that for the audience again. Patients with dependent rubor and pallor on elevation who have dependent-related ischemia worse at night and better when they hang their foot over the edge associated with hemodynamic pressure measurements or toe pressures, especially in diabetics, that corresponds to the ischemic pain. I think my definition of ischemic rest pain is pretty strict and very comparable to what most of the people in the audience would use as well.

Dr Larry Kraiss (Salt Lake City, Utah). Nice paper, Sam, but I think this is a paper that is begging for a comparison group or a control group, and I would ask what you think the results would be if you took your surgical patients and performed the same kind of analysis that you have shown us with your interventional treated patients.

The second thing I would ask is, I share your opinion that there is a difference between patients with tissue loss and rest pain, but I would argue that the patient with rest pain actually needs a more durable result perhaps than the patient with tissue loss, and so I want to know if you approach those patients differently in terms of your initial decision making.

Dr Ahn. That is a very good question, and I certainly agree with you and thank you for that suggestion, because you are right. We do not have a control group, and based on your suggestions, I will go back and look at the 58 patients that we excluded, look at them and compare to see how the open group did compared to this. But no matter what I do, this is a retrospective study, and what you are really implying is that we need to do a good prospective randomized trial. Now, Sam Wilson actually did that and reported it back about 10 years ago in a VA population and showed that there was no statistically significant difference between the open bypass vs the endovascular PTA group in patients with infrainguinal lesions. For iliac lesions there was a slightly better improvement in the open bypass, but it was only about a 10% difference.

Regarding your comments about the rest pain vs tissue loss, the rest pain patients can often be treated by just improving one level of occlusion. You don't need to get a perfect–most of these patients have multilevel disease. For tissue loss, you need to improve at least two, maybe three, and get good flow down to the foot, but for rest pain if you just take care of one level you will get them out of that rest pain, so oftentimes in these patients if you just take care of the inflow, say just the iliacs plus or minus the profunda, you don't need to do their SFA and tibials all the time to get them out of the rest pain. For rest pain, you do not have to get them perfect.

INVITED COMMENTARY

Joseph L. Mills, MD, *Tucson, Ariz*

The role of endoluminal therapy in the treatment of peripheral arterial disease is dramatically expanding.[1] Skeptics of endovascular therapy oft opine that PTA [percutaneous transluminal angioplasty] works best for those least in need of intervention, thus suggesting that PTA is reasonable for claudicants with focal lesions but has little to offer patients with critical limb ischemia (CLI). Ahn et al report a 10-year experience with a cohort of CLI patients managed by endoluminal therapy. Over the study period, 111 patients (128 limbs; 63% of total) with CLI were treated by PTA alone, whereas 76 limbs (37%) required open surgery. Technical success was 96%, clinical success was 93%, 30-day mortality was 0.9%, and long-term limb salvage was 89%. At first glance, these results in CLI patients after PTA are quite comparable to those of open surgery and seem astonishing. However, the devil is in the details.

The mean follow-up was short (14.7 months) and likely reflected not only a shift toward less invasive approaches in recent practice, but also the sobering reality that patients with CLI do not live long (5-year series mortality of 56%). Many malignancies have superior survival rates. In addition, 45% of patients had rest pain without tissue loss, and 33% required only iliac PTA. It is no surprise that PTA for hemodynamic iliac lesions often resolves ischemic rest pain. Results were predictably worse in patients with tissue loss and multiple, distal, or TransAtlantic Inter-Society Consensus D lesions. Primary patency was low (31% at 5 years), but secondary patency was 76%; this implies the necessity for reintervention. The authors do not provide the frequency, morbidity, or costs of repeat interventions. Primary patency, however, may not be the ultimate objective of CLI treatment. A 5-year clinical improvement rate (defined by Society of Vascular Surgery category) of 80% and a 6-year limb salvage rate of 89% are more meaningful end points.

What are the implications of this report? First, it is imperative that vascular surgeons become facile with thrombolysis, conventional PTA, subintimal angioplasty, newer technologies such as cutting balloons, and stent placement. These evolving therapies are applicable to an increasing percentage of our patients. Second, treatment outcomes require redefinition. Long-term patency should not be the Holy Grail of outcome assessment, particularly for CLI, in which symptom relief, lesion healing, and limb salvage, with minimal morbidity, are more critical end points. Open surgery offers excellent patency rates, but morbidity is significant.[2] Finally, it is clear that as the proportion of peripheral arterial disease patients effectively treated by endoluminal therapy expands, the numbers of open cases for practicing vascular surgeons and resident trainees will continue to wane. A recent report identified the difficulty in providing adequate numbers of open distal reconstructions for vascular surgical trainees because of the shift toward subintimal angioplasty.[3] New clinical training paradigms for residents and changes in the residency review committee case volume and distribution (open vs PTA) requirements will need to be rapidly implemented. Although there will be a role for tibial bypasses and complex, open reconstructions for the foreseeable future, "admit that the waters, around you have grown . . . for the times they are a changin'."[4]

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